

# TransFix<sup>®</sup>

## Certificate of Analysis TransFix<sup>®</sup> Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29830

 : 2021-05-28

Start Date of Manufacture: **2019-05-28**

Start Date of Quality Control Testing: **2019-05-30**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	70.1	69.7	0.6	PASS
% CD4+	61.6	60.6	1.6	PASS
CD3+ Abs Cnt	1148	1133	1.4	PASS
CD4+ Abs Cnt	707	686	3.0	PASS
CD8+ Abs Cnt	319	338	6.0	PASS
CD45+ Abs Cnt	1638	1625	0.8	PASS

### Pass Criterion:

The pass criterion is a less than 15% difference between the lymphocyte absolute count (CD45+ Abs Cnt), T cell absolute count and % (CD3+), T helper cell absolute count and % (CD4+) and cytotoxic T cell absolute count (CD8+) on day 0 and day 11.

### Comments:

3 separately stained tests were performed at each of the time points. These results were averaged and all parameters passed the acceptance criterion.

Signature of Quality Control Manager



Date: 21 JUNE 2019

